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BOARD OF PATENT APPEALS AND INTERFERENCES**

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Applicants : Mark J. Jaroszeski et al.
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For : Method of Using Electrical Fields to Facilitate the Entry of
Molecules in
Cells *In Vivo*

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Commissioner for Patents
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REPLY BRIEF

Sir/Madam:

In furtherance of its appeal from the Final Rejection mailed 14 June 2007 and in response to the Examiner's Answer mail dated February 08, 2008, Applicant hereby submits its Reply Brief in accordance with 37 C.F.R. 41.41.

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1. STATUS OF CLAIMS

Claims 1-2, 6, 8, 10, 21-22 and 24-28 are currently pending and under appeal. Claims 1-20 were originally pending in the application as filed. Claims 21-36 were added in Applicant's Amendment C (submitted 12 Feb 2003). Claims 37-52 were added in Applicant's Amendment E. Claims 3-5, 7, 9, 11-20, 23 and 29-52 have been subsequently cancelled. All of the pending claims have been rejected two or more times under 35 U.S.C. 102(e) over the art of record (i.e. U.S. Patent No. 6,678,558 B1 to Dimmer et al.) and the rejection has been made final.

2. GROUNDINGS OF REJECTION TO BE REVIEWED ON APPEAL

Whether the Office erred in rejecting claims 1-2, 6, 8, 10, 21-22 and 24-28 under 35 U.S.C §102(e) as being anticipated by U.S. Patent No. 6,678, 558 B1 to Dimmer *et al.*

3. ARGUMENT

The Office has taken a number of positions in the Examiner's Answer to the Appeal Brief. First the Office asserts that claim 5 of Dimmer anticipates Applicant's claims.¹ Second, the Office asserts that Dimmer's "agent movement signal" inherently anticipates the claims at issue.² Lastly, the Office asserts that a plurality/series of pulses can equate to a "single continuous electric field..." or a "continuous electric field" having a "duration of 200 ms. to 20 minutes."^{3, 4} Each of these assertions will be addressed in turn below.

I. Dimmer's claim 5 does not implicitly or inherently anticipate the claims on appeal

The Office has rejected Applicants' claims under 35 U.S.C. 102(b) with reference to claim 5 of U.S. Patent No. 6,678,558 B1 to Dimmer et al. ("Dimmer"). The principal assertion of *Applicant* is that Dimmer does not explicitly (expressly) teach each element of the claim under consideration (i.e. there is missing descriptive material with respect to the claim limitations at issue vis-à-vis the Dimmer patent). In particular, Dimmer does not expressly teach applying a continuous electric field in the range of 1mV/cm to 200V/cm to the target tissue for a duration of 200 ms. (as claimed in independent claims 1 and 21). It is further submitted that Dimmer does not implicitly or inherently disclose the elements at issue.

"The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103."⁵ It is submitted that an express disclosure of subject matter corresponding to a limitation would be one where the subject matter is explicitly stated and would be capable of pinpoint citation in support of a rejection, with little or no explanation in support of the pinpoint citation (i.e the cited section would essentially be self-explanatory). Where the disclosure is implicit or inherent, additional support must be made in support of a rejection and additional requirements must be addressed. In particular, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the

¹ Examiner's Answer mail dated Feb. 08, 2008 at pages 5-7.

² Examiner's Answer mail dated Feb. 08, 2008 at pages 7-8.

³ Examiner's Answer mail dated Feb. 08, 2008 at pages 7-8.

⁴ See also Applicant's independent claims 1 and 21.

⁵ See MPEP 2112 – Requirements of Rejection Based on Inherency – Burden of Proof.

inherency of that result or characteristic.”⁶ “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”^{7, 8} Probabilities or possibilities are not sufficient.

It should be noted that the Office has not asserted inherency, although this appears to underlie their stated position because they are backing into the limitation based upon other aspects of the Dimmer disclosure. Furthermore, the Office *is not* making the rejection under 35 U.S.C. §103(a), although reliance on §103(a) might allow the Office to pick amongst different portions of the cited reference to make a *prima facie* showing, assuming other aspects of a showing could be made. However, *neither* has the Office made an explicit showing of the elements at issue with respect to the Dimmer patent. Instead, the Office has backed into the missing elements by asserting that they would be mathematically possible within the limitations of a particular claim, a claim not specifically addressing the limitation at issue.

Claim 1 of the application recites in relevant part:

1. A method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of the steps of:

...

applying an electric field to the target tissue, the application of the electric field consisting of a single continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes; and ...

⁶ See MPEP 2112 citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

⁷ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

⁸ See also MPEP 2112 - Requirements of Rejection Based on Inherency; Burden of Proof - "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Claim 21, the other independent claim on appeal, is similarly directed. All of the claims on appeal have been rejected under 35 U.S.C. 102(b) over Dimmer with reference to claim 5 of Dimmer⁹, which is directed as follows:

1. A method for, co delivering an agent to a cell comprising:

(a) positioning two or more electrodes relative to the cell such that one or more therapeutic electrical signals can pass between at least two of the electrodes and through the cell; and

(b) passing one or more therapeutic electrical signals between at least two of the electrodes to make an electroporated cell, wherein at least one of therapeutic electrical signals simultaneously comprises an agent movement signal and an electroporation signal, wherein the electroporation signal has a frequency greater than about 10 KHz; and

(c) contacting the electroporated cell with the agent to effect delivery of the agent to the cell.

5. A method according to claim 1 wherein the therapeutic electrical signal is comprised of 1 to about 1,000,000 pulses.

The Office provides some analysis in regards to the disclosure of the elements at issue in the Office Action. The Office states that “[i]t is respectfully pointed out that Dimmer explicitly claims an electroporation method wherein the electroporation method can comprise 1 to 1,000,000 pulses (e.g. see claim 5).” Applicant does not challenge the assertion that there may be anywhere from 1 to 1,000,000 pulses in Dimmer’s methodology. However, the issue is not the number of pulses, but the duration of the pulse or pulses making up the 1 to 1,000,000 pulses.

The Office then states that “Claim 5 does not explicitly indicate the duration of each pulse.” Again, Applicant does not challenge this assertion. In fact, if the point that the Office cites in making a case for anticipation “does not explicitly indicate the duration of each pulse”, then the reference does not expressly provide the teaching sought to be shown in making a case for anticipation. Therefore, it would appear that the Office is arguing some form of inherency if a rejection is to be made under 35 U.S.C. §102.

Given that the claim does not indicate a duration, then one must look to the immediately surrounding claims (i.e. claims within the same grouping/dependency) for context. The very next claim, claim 6, is dependent upon claim 5 and specifies that “each

⁹ See page 6 of the Examiner’s Answer where it is stated “In response, it is respectfully pointed out that Dimmer explicitly claims an electroporation method wherein the electroporation method can comprise 1 to 1,000,000 pulses (e.g. see claim 5).”

pulse has a duration of about 2 to about 50 μ s.” While one might be tempted to reflexively respond that limitations from claim 6 cannot be necessarily imported into claim 5, such a response would only be apposite on the issue of the scope of claim 5, not the extent of the teaching that can properly be attributed to such a claim. Simply because claim 5, by itself, is not so limited by the recitation of claim 6, one cannot assume any longer pulse duration than 50 μ s as recited in claim 6. The claims must be taken in context, and one cannot look to extrinsic areas of the specification where context is provided in the surrounding claims.¹⁰ None of the other surrounding claims directly address the duration of a single pulse or “continuous electric field” as claimed.

However, claims 7-9 further limit claim 5 and refer to durations, though not pulse durations. These claims specify that “the therapeutic electric signal includes a plurality of pulses” and limit the *total pulse duration* of that plurality of pulses to be, for instance, less than about 10 seconds. However, one cannot say how many pulses there would be once the therapeutic electrical approached 10 seconds. A reasonable conclusion would be that, as the total pulse duration increases, so would the number of pulses making up that total pulse duration. There is simply no reason, in choosing among the various options of between 1 and 1,000,000, to choose 1 pulse. And while the claims would not exclude a signal pulse, the mere fact that a claim would not exclude something does not equate to a teaching of all things not excluded or mathematically possible within that context.

Additionally, a well-known canon of statutory construction is the maxim ‘*Expressio unius est exclusio alterius*’ (The express mention of one thing excludes all others). The rule is based upon the presumed intent of the drafter. A drafter, when faced with the task of drafting rules or regulations, is presumed to have taken the time to carefully consider the words chosen to express the limits of the rules. Where the drafter went to the extent of setting out express limits, or classes of things, to which the rules apply, a strong presumption exists that things falling outside of those limits were intended by the drafter to be excluded. Clearly, Dimmer carefully considered pulse durations. Yet he limited his claims to pulse durations of about 2 to about 50 μ s. In a similar vein Dimmer considered longer time frames. However, he only claimed those in the context of

¹⁰ e.g. see the textual canon of interpretation *Noscitur a sociis* (A word is known by the company it keeps) When a word is ambiguous, its meaning may be determined by reference to the rest of the statute.

a “therapeutic electric signal”, which can have up to 1 million pulses. Thus, given that Dimmer clearly considered pulse durations and clearly considered longer time frames, a strong inference arises that Dimmer rejected or failed to give consideration to pulse durations in excess of 50 μ s.

The specification contains additional evidence supporting this conclusion. First, the longest pulse duration specifically referred to by Dimmer as effecting the electropermeabilization of cells is 50 μ s. Second, Dimmer is advocating the use of pulse durations of increasingly short duration to increase the frequency, thereby effecting a reduced discomfort as discussed on pages 12-14 of Applicant’s Appeal Brief.

The Office states on page 6 of the Examiner’s Answer that:

Claim 5 does not explicitly indicate the duration of each pulse; however, looking to the specification it is clear that the “total electroporation duration signal” can be “preferably less than about 10 seconds” and “most preferably about 50 μ s-400ms”. Therefore, if the total number of pulses is 1 (as is taught by at least claim 5 of Dimmer) then the “total electroporation duration signal” of that single pulse can be “preferably less than about 10 seconds” and “most preferably about 50 μ s-400ms.” Therefore, Dimmer does teach a single pulse that is within the limitations of the instant claims.

This raises a number of issues. First, the Office is pointing disparate portions of the specification in making the case for anticipation based upon claim 5. However, as was indicated in Applicant’s Appeal Brief, “[t]o find anticipation the identical invention must be shown in as complete detail as is contained in the claim with the elements arranged as required by the claim.”¹¹ For a rejection under 35 U.S.C. 102 to be proper, the cited reference must clearly and unequivocally disclose the claimed subject matter; the Office may not pick and choose among different options or elements from various portions of the specification or as found in different embodiments to produce the claimed invention for the purpose of a rejection for anticipation.^{12,13} Such picking and choosing would require making a case under 35 U.S.C. 103(a).

¹¹ See MPEP 2131 providing “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ...The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

¹² “When the claimed invention is not identically disclosed in a reference, and instead requires picking and choosing among a number of different options disclosed by the reference, then the reference does not anticipate. *Akzo N.V. v. International Trade Commission*, 808 F.2d 1471, 1480 (Fed. Cir. 1986), cert.

Second, as was indicated on pages 13-14 of Applicant's Appeal, the total electroporation signal duration is the sum of the total number of pulses. Dimmer specifically indicates that there may be from 1 to 1 million pulses. The Office resorts to conjecture when it is stated that *if* the total number of pulses is 1 within Dimmer's range of time frames for the total electroporation signal duration. Such conjecture has been held unsupportable in the context of a rejection under 35 U.S.C. 103(a); it would hardly be more acceptable under 35 U.S.C. 102.¹⁴ With respect to teachings and support in a disclosure it has been held that "[i]t is 'not a question of whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device.'"¹⁵ The Office is picking a tree in a large and dense forest where the blaze marks of Dimmer do not lead to that tree.^{16, 17} The tree picked, namely the number of pulses, then allows the Office to back into the desired pulse duration by selecting from another forest of ranges, namely the total electroporation signal duration, to suit the rejection. Such selective choosing is not the essence of an inherent disclosure sufficient to support a rejection under 35 U.S.C. 102(b).

The Office closes this section by stating on pages 6-7 of the Examiner's Answer:

Applicants appear to be focusing on the "preferable" and "most preferable" embodiments that are taught by Dimmer. However, Dimmer teaches more than the "preferable" and "most preferable" embodiments Applicants focus on. Considering the complete teaching of Dimmer, it is clear that

denied, 107 S. Ct. 2490 (1987); In re Arkley, 455 F.2d 586, 587-88 (CCPA 1972)." *Mendenhall v. Astec Industries, Inc.*, 13 U.S.P.Q.2d (BNA) 1913, 1928, 1988 WL 188449 (E.D. Tenn. 1988), *judgment aff'd*, 887 F.2d 1094, 13 U.S.P.Q.2d (BNA) 1956 (Fed. Cir. 1989)

¹³ "[F]or the instant rejection under 35 U.S.C. § 102(e) to have been proper, the Flynn reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection."

Application of Arkley 59 C.C.P.A. 804, 807, 455 F.2d 586, 587 - 588 (Cust. & Pat.App.1972).

¹⁴ *Application of Ruschig* 54 C.C.P.A. 1551, 1557, 379 F.2d 990, 995 (Cust. & Pat.App.,1967).

¹⁵ *Martin v. Mayer* 823 F.2d 500, 505 (C.A.Fed.,1987).

¹⁶ "It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared- or have not yet been made, which is more like the case here- to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none." *Application of Ruschig* 54 C.C.P.A. 1551, 1557, 379 F.2d 990, 995 (Cust. & Pat.App.,1967).

¹⁷ "As *Ruschig* makes clear, one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention." *Purdue Pharma L.P. v. Faulding Inc.* 230 F.3d 1320, 1326 (C.A.Fed.,2000).

Dimmer teaches an electroporation method that can be 1 to 1,000,000 pulses wherein the total duration of the electroporation signal is less than 10 seconds. As such, Dimmer teaches an electroporation method comprising 1 pulse and having a duration of less than 10 seconds, and most preferably about 50 μ s-400ms.

The durations listed by the Office above can be found at col. 10, lines 54-58 and made with reference to the “total electroporation signal duration”, not the pulse duration. The Office appears to be taking the position that pulses/therapeutic electric signals (as specified in col. 10, line 12-16) are the same as total electroporation signal durations (as specified in col. 10, lines 55-60). The two are not the same. (The differences between the two are analogous to the differences between claim 6 of Dimmer and claims 7-9 of Dimmer.) First, it is explicitly stated that the total electroporation signal duration is the sum of first polarity and second polarity duration of each electroporation signal (col. 10; line 53) and that there can be 1-1,000,000 pulses (col. 10; line 59) in the total electroporation signal duration. Second, statements made about the duration of each by Dimmer are incongruous to their being the same. With respect to the total electroporation signal duration Dimmer states at col. 10, lines 54-58:

The total electroporation signal duration is preferably less than about 10 seconds, more preferably about 30 μ s-10 seconds, even more preferably about 30 μ s-1 ms and ***most preferably about 50 μ s-400 ms.*** (emphasis added)

With respect to the pulses/therapeutic electric signals Dimmer states at col. 10, lines 12-19:

Therapeutic electrical signals according to the present invention preferably have a pulse duration of less than about 50 μ s, more preferably have a pulse duration of less than about 12.5 μ s and ***most preferably a pulse duration of less than about 5 μ s.*** In one embodiment of the invention, the pulse duration is about 80 ns-50 μ s and in another embodiment of the invention the pulse duration is about 2 μ s-50 μ s. (emphasis added)

Two important points must be made with respect to the Office’s position. First, if the total electroporation signal duration and the therapeutic electrical signals were referring to the same thing, then Dimmer would be advocating in one place that pulse durations were ***most preferably*** less than about 5 μ s while advocating in another (only a paragraph or so below) that pulse durations ***most preferably*** about 50 μ s-400 ms. This would not make sense if both were referring to the same thing. It is only in the context of these being different that such statements make sense.

Second, while Dimmer is admittedly referring to the therapeutic electrical signals according to the present invention *preferably* have a pulse duration of less than about 50 μ s, this begs the question of where Dimmer expressly discloses longer pulse durations as effecting a change in porosity of the cell having a duration in excess of 50 μ s. The Office has characterized Applicant as “focusing on the ‘preferable’ and ‘most preferable’ embodiments.” However, these appear to be the only express embodiments of pulse durations taught by Dimmer that effect a change in porosity. And these express embodiments at 50 μ s are far shorter than the minimum duration of 200 ms. (as claimed in independent claims 1 and 9).

As a final note on semantics, the Office has closed by prefacing with the phrase “Considering the complete teachings of Dimmer ...”¹⁸ It is not the complete teachings that are to be considered in making a showing under 35 U.S.C. 102, but rather the specific teachings.^{19, 20, 21} It is only in the context of a rejection under 35 U.S.C. 103(a) that the complete teachings of a reference are to be considered. That the Office would choose such wording tends to evidence the mental processes underlying the rejections, showing that they were really thinking in terms of obviousness and not anticipation. Furthermore, in making a rejection under 35 U.S.C. 103(a) one would need to address additional aspects, such as the motivation to make the proposed change. Such a showing

¹⁸ Examiner’s Answer at page 7, first sentence.

¹⁹ See MPEP 2131 providing “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ...The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

²⁰ “When the claimed invention is not identically disclosed in a reference, and instead requires picking and choosing among a number of different options disclosed by the reference, then the reference does not anticipate. *Akzo N.V. v. International Trade Commission*, 808 F.2d 1471, 1480 (Fed. Cir. 1986), cert. denied, 107 S. Ct. 2490 (1987); *In re Arkley*, 455 F.2d 586, 587-88 (CCPA 1972).” *Mendenhall v. Astec Industries, Inc.*, 13 U.S.P.Q.2d (BNA) 1913, 1928, 1988 WL 188449 (E.D. Tenn. 1988), *judgment aff’d*, 887 F.2d 1094, 13 U.S.P.Q.2d (BNA) 1956 (Fed. Cir. 1989)

²¹ “[F]or the instant rejection under 35 U.S.C. § 102(e) to have been proper, the Flynn reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection.” *Application of Arkley* 59 C.C.P.A. 804, 807, 455 F.2d 586, 587 - 588 (Cust. & Pat.App.1972).

would be extremely difficult given that Dimmer is strongly advocating shorter pulse durations to reduce patient discomfort. Therefore, one faced with Dimmer would not be motivated to increase pulse durations.

II. Dimmer's "agent movement signal" does not anticipate the claims at issue

The Office has asserted that the agent movement signal meets the claim limitations by having the same method steps, thus producing the same results, and therefore anticipates Applicants' claims.²²

The agent movement signal taught by Dimmer does not explicitly or inherently anticipate the Applicant's claims.²³ Applicant's claim 1 recites, in relevant part, "applying an electric field to the target tissue, the application of the electric field consisting of a single continuous electric field in the range of 1 mV/cm to 200V/cm applied for a duration of 200 ms. to 20 minutes..." Dimmer teaches that "[t]he agent movement signal preferably have a potential of about 5V-200V and more preferably about 10-100V. Additionally, the duration of the agent movement signals is preferably about 100 μ s-10 seconds."²⁴

Thus, Applicant's claim a field strength "consisting of a single continuous electric field in the range of 1 mV/cm to 200V/cm..." Dimmer is silent as to the field strength of the agent movement signal.

The Office states in the Examiner's Answer that:

Dimmer also teaches applying an agent movement signal having a potential of about 5V-200V and more preferably about 10V-100V, having a duration of preferably about 100 μ s-10 seconds. Therefore, Dimmer teaches administration of an electric signal that meets the voltage and duration requirements of the claims. As such, the administration of the "agent movement signal" as described by Dimmer, would necessarily have the same result as the claimed method. In other words, since the agent movement signal taught by Dimmer meets the voltage and duration limits of the claims it must have the same effect on the cells.

However, the claims do not specify a voltage (V) requirement. The claims specify a range for the electric field (i.e. V/cm). The claims call for an electric field in the range of 1 mV/cm to 200V/cm. To compute an electric field from the voltage as provided by Dimmer, one would need to know the distance between the electrodes. Without that

²² Examiner's Answer at page 7, bottom of the page.

²³ See U.S. Patent 6,678,558 B1 at column 14, lines 9-44 for Dimmer's "agent movement signal."

²⁴ U.S. Patent 6,678,558 B1 at column 14, lines 31-34.

knowledge, one could not convert Dimmer's specified voltage of 5V-200V into an electric field. Without knowing the electric field, one could not establish whether this teaching meets the limitation of the claim or whether it would be sufficient to effect a change in porosity (as recited by the independent claims of the instant application). Furthermore, it should be noted that elsewhere in the specification with respect to the electroporation signal Dimmer refers to field strengths (V/cm) and not potential (e.g. col. 10, lines 29-47). Clearly, Dimmer considered aspects of his invention in terms of field strength and expressed himself accordingly. Therefore clearly he was capable of being more precise, but chose to teach nothing more with respect to his agent movement signal as presented in column 14, lines 9-44. Therefore, it cannot be said to be a substantially identical process because Dimmer does not teach the step of "applying an electric field to the target tissue, the application of the electric field consisting of a single continuous electric field in the range of *1 mV/cm to 200V/cm ...*" Based upon the section cited by the Office, one would not be able to say what field strength is taught by Dimmer.

Furthermore, Applicant's claimed method results in the electroporation/electropermeabilization of cells. Dimmer describes his agent movement signal as moving the agent toward the cell, but requiring different conditions to effect electroporation. At column 7, lines 19 through 40 Dimmer states:

[T]he therapeutic electrical signals include electroporation and/or agent movement signals. *The electroporation signals serve to temporarily create pores in the cells of the treatment site 30* without causing permanent cell damage. One or more agents, such as genes and/or drugs, can be delivered to the treatment site 30 before, after or during the application of the therapeutic electrical signals. These agents can enter the cells within a treatment site 30 through the pores created by the electroporation signals.

The agent movement signals cause movement of an agent relative to cells. Certain agents in suspension are known to move through the suspension in response to application of an electric field. The agent movement signals provides the electric field which provides motion to the agents. This movement is generally in a particular direction relative to the applied field. Due to the size difference between cells and the agent, this movement can drive an agent toward a cell. *When electroporation signals have created pores in the cell,* the movement of the agent increases the opportunity for the agent to enter the cell through the opening. As a result, the agent movement signals can increase the efficiency of an electroporation treatment. (emphasis added)

Therefore, contrary to the assertion of the Office, the agent movement signal does not utilize the same method steps, nor does it achieve the same results. In light of the

foregoing, it is respectfully submitted that Dimmer's agent movement signal does not anticipate Applicants' claimed methods.

III. A plurality of pulses does not equate to a continuous electric field

The Office has asserted that "the 'continuous electric field' of the claims is NOT limited to a single pulse; rather, the continuous electric field' can comprise multiple electric pulses."²⁵ Applicant respectfully disagrees with this interpretation and further asserts that it is not consistent with the prosecution history for the application.

An electric field is a vector field with SI units of newtons per coulomb (N C^{-1}) or, equivalently, volts per meter (V m^{-1}).²⁶ An electric pulse involves the application of voltage across electrodes. At the instant immediately preceding a pulse and immediately following a pulse the electric field would be null. Similarly, during the application of a series of pulses, in between each pulse in a series of pulses, one would expect, without more, the field would fall to null for a brief period of time. The electric field would thus be discontinuous between each pulse as the applied voltage across the electrodes returns to zero. Therefore, multiple electric pulses would involve a series of electric fields where the fields would be discontinuous between each pulse.

The Office has asserted that a continuous electric field can be a plurality of pulses. In making this assertion the Office refers to claims 21 and 24.²⁷ Claim 21 uses comprising language and recites in relevant part "applying a continuous electric field in the range of 1mV/cm to 200V/cm to the target tissue for a duration of 200ms to 20 minutes ...". Claim 24 recites "[t]he method recited in Claim 21, wherein *the applying step comprises applying a plurality of substantially continuous electric pulses* of between 1mV/cm and 200V/cm to the target tissue, wherein the duration of each substantially continuous electric field is sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of the cell." (emphasis added) While claim 24 may be inelegantly worded (i.e. referring to "substantially continuous electric pulses" in one part of the claim and "substantially

²⁵ Examiner's Answer, page 8 at the bottom of the page.

²⁶ Wikipedia under the topic "electric field" as accessed on April 4, 2008.

²⁷ Examiner's Answer, page 9 at the top of the page.

continuous electric field” in another part of the claim; referring to “continuous electric pulses” rather than “continuous electric fields” as in claim 21; referring to the continuity as “substantially continuous” as opposed to “continuous” as in claim 21; *but note the interchangeable use of the terms “field” and “pulse” and the fact that the Examiner did not reject due to ambiguity or object due to lack of antecedent basis*), such wording would not alter the fact that the electric field would drop to null in the interim between consecutive pulses as discussed above.

The Office states on page 9 of the Examiner’s Answer that “given the broadest reasonable interpretation of the claims consistent with the disclosure, the ‘continuous electric field’ of the claims is not limited to a single pulse, but actually encompasses ‘a plurality’ of pulses.”²⁸ Such an interpretation is an unreasonable one for at least a couple of reasons.

First, claim 24 **does not recite** “wherein *the continuous electric field* comprises applying a plurality of substantially continuous electric pulses ...” It recites “wherein *the applying step* comprises applying a plurality of substantially continuous electric pulses ...” Yet the Examiner would rewrite/interpret the claim as though it recites the former rather than the latter.

Second, such an interpretation as the Examiner provides of the phrase at issue renders claim 24 redundant to claim 21. Such an interpretation is not reasonable. “The law has long recognized that each individual claim constitutes a separate invention....[U]nder the doctrine of claim differentiation a claim construction that renders one claim superfluous to another is ‘presumptively unreasonable’ and should, where possible, be avoided.”^{29, 30} Similarly, interpretations that render terms superfluous are to be avoided over interpretations that give life and meaning to each word or term. If the term in claim 21 reciting a “continuous electric field” could be construed as covering a plurality of pulses, then there would be no purpose to claim 24, and it should be

²⁸ Examiner’s Answer, page 9 at the top of the page.

²⁹ Annotated Patent Digest § 5:64 (Database updated March 2008) § 5:64. Avoid interpretations that render a claim redundant with another claim.

³⁰ See also *Beachcombers v. WildeWood Creative Products, Inc.*, 31 F.3d 1154, 1162, 31 U.S.P.Q.2d (BNA) 1653 (Fed. Cir. 1994) (interpretation of claim that resulted in it having the same scope as another claim improper, rather claim would be interpreted to give “significance to the distinction between claims 1 and 9”); *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574, 225 U.S.P.Q. (BNA) 236, 239 (Fed. Cir. 1985).

objected to as failing to further limit claim 21. However, the Examiner has not done this, because this is not consistent with his prior interpretation of the claims.

Based upon the foregoing, it is respectfully submitted that the phrase “continuous electric field” is not anticipated by a teaching of a plurality of pulses.

4. CONCLUSION

Applicant respectfully submits that the rejection of claims 1-2, 6, 8, 10, 21-22 and 24-28 under 35 U.S.C. 102(e) is improper and should be withdrawn. Fairness to Applicant requires reversal of the final rejection; therefore, such reversal is solicited.

Very respectfully,

SMITH & HOPEN, P.A.



By: _____

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CERTIFICATE OF ELECTRONIC TRANSMISSION
(37 C.F.R. 2.190 (b))

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on April 8, 2008.

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/lauren reeves/

Lauren Reeves